DEPARTMENT OF THE ARMY
HEADQUARTERS, U. S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO
ATTENTION OF

OTSG/MEDCOM Policy Memo 08-031

21 JUL 2008

MCHO-CL-C

Expires 21 July 2010

MEMORANDUM FOR Commanders, MEDCOM Regional Medical Commands

SUBJECT: Implementation Guidance: New Women's Readiness Guidelines

1. References:

a. American Society for Colposcopy and Cervical Pathology (ASCCP), "2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Screening Tests", Journal of Lower Genital Tract Disease, 11(4): 201-222, October 2007, American Society for Colposcopy and Cervical Pathology, http://www.jlgtd.com/pt/re/jlgtd/pdfhandler.00128360-200710000-00001.pdf;jsessionid=H2TPGsBycMx1msLhHQtNXCp6Fj6smDVpxjTGhjGpQKynHnNG7PxL!132671813!181195628!8091!-1

b. ASCCP, "Consensus Guidelines Algorithms 2007", 2007, ASCCP, Oct 2007, http://www.asccp.org/pdfs/consensus/algorithms_cyto_07.pdf

c. ACOG Clinical Management Guidelines for Obstetrician-Gynecologists, Number 45, August 2003, Cervical Cytology Screening, Obstet Gynecol, 2003 Aug; 102 (2): 417-27

d. Preventive Services Task Force, *Screening for Breast Cancer: Recommendations and Rationale,* February 2002, Agency for Healthcare Research and Quality, Rockville, MD, http://www.ahrq.gov/clinic/3rduspstf/breastcancer/brcanrr.htm

e. U.S. Preventive Services Task Force, *Screening for Chlamydial Infection*, Topic Page, June 2007, Agency for Healthcare Research and Quality, Rockville, MD, http://www.ahrq.gov/clinic/uspstf/uspschlm.htm

f. AR 40-501, Standards of Medical Fitness, 2008

2. Purpose: To provide implementation guidance for new women's readiness categories in Medical Protection System (MEDPROS) as well as to direct the criteria to be used for evaluation, treatment and follow up of abnormal cytology.

3. Proponent: The proponent for this implementation guidance is Clinical Services Division, Health Policy and Services Directorate.

4. Background: A new guideline for evaluation and treatment of abnormal cervical cytology has been released by the American Society for Colposcopy and Cervical Pathology (ASCCP). The new ASCCP guidelines differentiate treatment and follow up of abnormal cytology for women 20 years of age and younger from those over 20 years of age. MEDCOM will follow these national standards for the evaluation and treatment of abnormal cervical cytology. In addition, national guidelines will be followed for the performance of mammography for breast cancer screening and for the performance of chlamydia screening.

5. Responsibilities:

a. Regional Medical Commands (RMCs) are responsible for the execution of this policy.

b. Local MTFs will develop procedures to ensure the Soldier's PAP results are assigned a category as outlined below and entered into MEDPROS. They will also assure that chlamydia and mammogram screenings are entered into MEDPROS as those modules become available in MEDPROS.

6. Policy:

a. Female Soldiers are required to have an annual PAP smear unless they meet one of the following criteria:

(1) They are 30 years of age or older with no history of dysplasia in the past and they have had three consecutive normal PAP smears. These women are required to have PAP smears/cervical cytology every three years.

(2) The Soldier has had a hysterectomy with removal of the cervix for reasons other than cervical dysplasia or cancer. She is permanently exempt from the PAP smear. Those with a history of supracervical hysterectomy (cervix present) do not apply for permanent exemption.

b. Female Soldiers age 25 years or younger are required to have annual Chlamydia testing.

c. Women age 40 and over are required to have a mammogram a minimum of every 2 years. More frequent intervals may be indicated based on patient risk factors and clinical judgment.

d. Women's Health Readiness Categories are as follows (See enclosure 1 which provides guidance on timing of pre-deployment cytology screening):

(1) Women's Readiness Class 1:

(a) Soldier has normal cervical cytology within one year or

(b) Soldiers 30 years of age and over who have met the criteria in 6.a, and has normal cytology within 3 years.

(c) Soldier will be considered available and categorized as "Green" in MEDPROS.

(2) Women's Readiness Class 2:

(a) Soldiers over 20 years of age with ASC-US HPV negative or

(b) Soldiers 20 years old and younger who have a history of abnormal cervical cytology to include cervical cytology showing Atypical Squamous Cells of Undetermined Significance (ASC-US) with Human Papilloma Virus (HPV) typing negative or positive for oncogenic HPV or those with low-grade squamous intraepithelial lesion (LSIL) or cervical intraepithelial neoplasia 1 (CIN 1) or

(c) Soldiers of any age with abnormal cervical cytology which has been fully evaluated and/or treated and has been cleared by a provider credentialed in women's health.

(d) These Soldiers will be considered available and categorized as "Green" in MEDPROS.

(3) Women's Readiness Class 3: Soldier's most recent cervical cytology is abnormal and requires further evaluation by a provider with credentials in women's health. The following cervical cytology results require further evaluation:

(a) In women over 20 years of age this includes: ASC-US HPV Positive, LSIL, HSIL, any CIN, CIS, adenocarcinoma in situ (AIS), atypical glandular cells (AGC), or invasive cancer.

(b) In women 20 years and younger this includes: HSIL, CIN 2, CIN3, CIS, AIS AGC, or invasive cancer.

(c) Soldier will be considered non-available and categorized as "Red" in MEDPROS.

(4) Women's Readiness Class 4: Soldier whose cervical cytology is not current as defined in 6.a. Soldiers will be considered non-available and classified as "Red" in MEDPROS.

e. In preparation for MEDPROS entry of readiness classifications, RMCs will need to identify those personnel in MTFs and or SRP sites that will need to have write access to update this information for the supported population. Personnel needing access will need to complete a NISA-9R form (Enclosure 3). If you have any questions regarding the completion of the NISA-9R form, please contact the MODS Help Desk at 703.681.4976 or DSN 761.4976. A special "Women's Readiness" web site will be created in MEDPROS Web Data Entry (MWDE) that only those personnel identified by the MTFs will have access to update this Women's Health information. No other personnel will have write access to this module. A Women's Readiness "How To" manual will be published and fielded in the near future that will provide instructions on the posting of this important information.

f. There will be transition period from 1 August 2008 thru 1 August 2009 for the implementation of new Women's Readiness Class (WRC) Logic in MEDPROS. Those personnel whose latest PAP/cytology date posted in MEDPROS is prior to 1 August 2008 will be measured for compliance using the current MEDPROS logic: If the cytology date is less than one year old, it will be considered current for that requirement and a date greater than one year will be considered non-compliant. Cytology performed after 1 August 2008, must be entered in MEDPROS following the new WRC requirements: Soldiers who become due for cytology must have the "PAP" date, WRC, and next due date posted in the MEDPROS Web Data Entry Module. Those who are WRC 1 and 2 will be considered available (Green/Go); those classified as WRC 3 or 4 will be considered unavailable (Red/No-Go). At that time, MEDPROS will also have the ability to post "Exempt" for those personnel no longer required to have Pap test performed and they will be classified as WRC 1.

g. Evaluation, treatment and follow up of abnormal cervical cytology will be based on the most current ASCCP Guidelines.

h. In support of the current ASCCP guidelines, a HPV-DNA test only without PAP smear (performed by brush with Digene's HC2 DNA Collection Device) will be submitted by the MTF lab to one of the three reference labs that can perform the testing. The reference labs for this test are presently located at BAMC, WRAMC and MAMC. Please see enclosure 2; Walter Reed Cytopathology Bulletin: HPV DNA Test Utilization for proper collection and indications for usage.

i. Providers conducting PAP smears/cervical cytology should counsel all female Soldiers per current CDC guidelines (presently up to age 26) about the benefits of the HPV vaccine and encourage the vaccine for these women.

7. These new guidelines will not change present Unit Status report (USR) reporting criteria.

8. This policy represents the minimum requirements for screening and is not a substitute for clinical judgment. More stringent screening may be indicated in selected populations with additional risk factors.

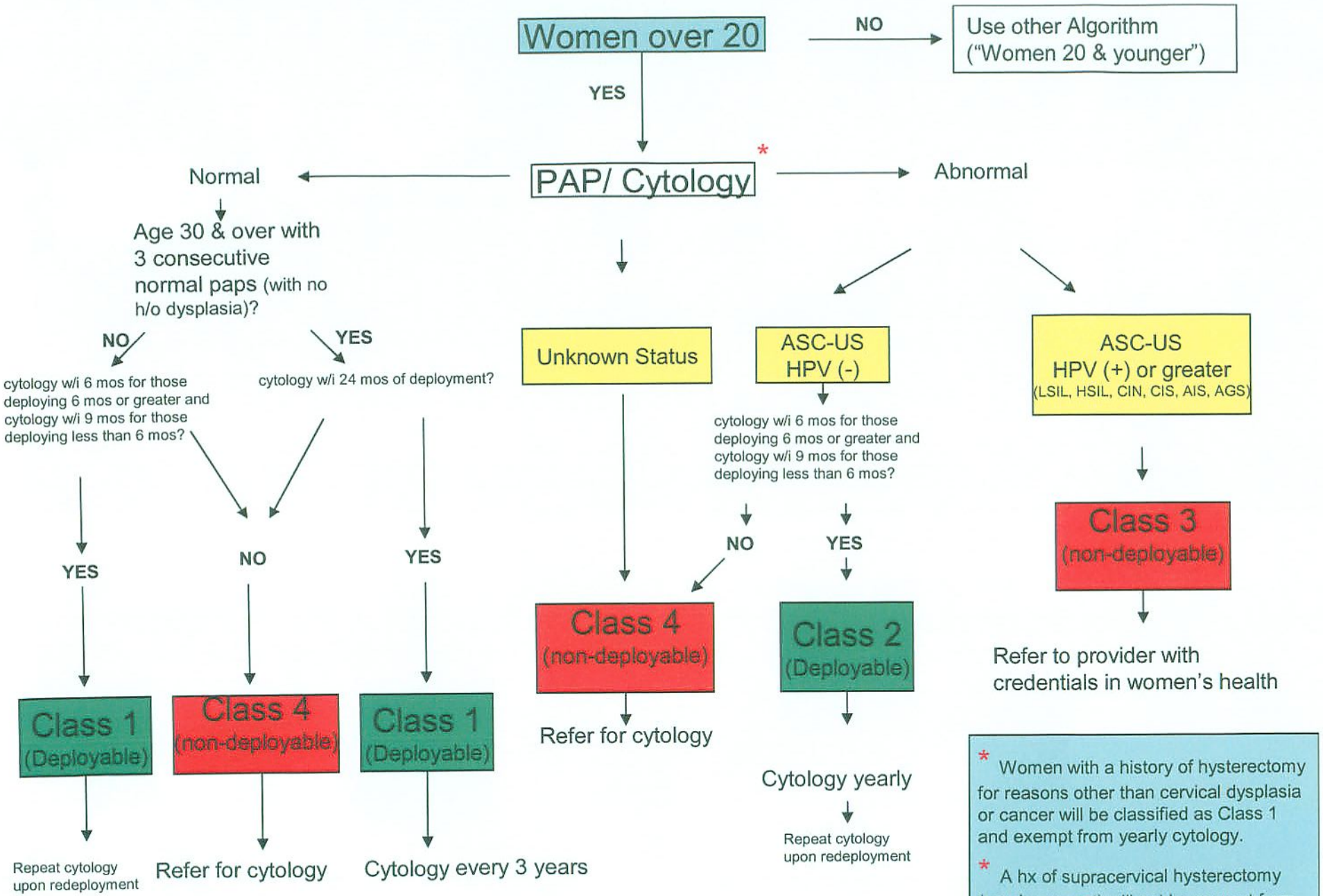
9. Policy implementation is 1 August 2008.

FOR THE COMMANDER:

William H Thresher

WILLIAM H. THRESHER
Chief of Staff

Encls

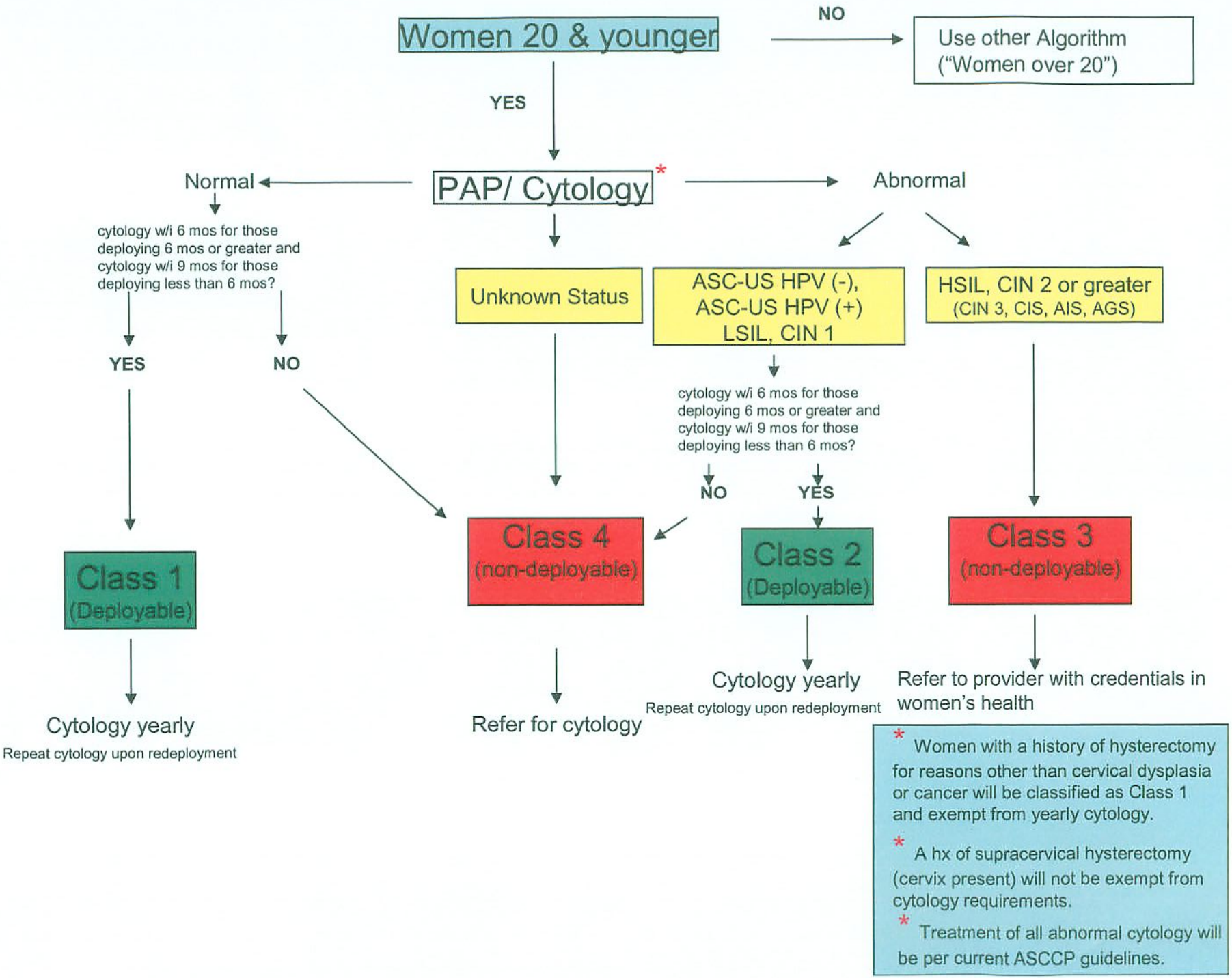


* Women with a history of hysterectomy for reasons other than cervical dysplasia or cancer will be classified as Class 1 and exempt from yearly cytology.

* A hx of supracervical hysterectomy (cervix present) will not be exempt from cytology requirements.

* Treatment of all abnormal cytology will be per current ASCCP guidelines.

ENCL 1


Women 20 & younger
NO
Use other Algorithm ("Women over 20")
YES
PAP/ Cytology *
Normal
Abnormal
cytology w/i 6 mos for those deploying 6 mos or greater and cytology w/i 9 mos for those deploying less than 6 mos?
YES
NO
Unknown Status
ASC-US HPV (-), ASC-US HPV (+) LSIL, CIN 1
HSIL, CIN 2 or greater (CIN 3, CIS, AIS, AGS)
cytology w/i 6 mos for those deploying 6 mos or greater and cytology w/i 9 mos for those deploying less than 6 mos?
NO
YES
Class 1 (Deployable)
Class 4 (non-deployable)
Class 2 (Deployable)
Class 3 (non-deployable)
Cytology yearly
Repeat cytology upon redeployment
Refer for cytology
Cytology yearly
Repeat cytology upon redeployment
Refer to provider with credentials in women's health
* Women with a history of hysterectomy for reasons other than cervical dysplasia or cancer will be classified as Class 1 and exempt from yearly cytology.
* A hx of supracervical hysterectomy (cervix present) will not be exempt from cytology requirements.
* Treatment of all abnormal cytology will be per current ASCCP guidelines.

ENCL 1

WALTER REED ARMY MEDICAL CENTER

Walter Reed National Military Medical Center
Department of Pathology and
Area Laboratory Services

CYTOPATHOLOGY BULLETIN:
HPV DNA Test Utilization

The American Society of Colposcopic and Cervical Pathology (ASCCP) published new consensus management guidelines for abnormal Pap tests in October 2007. Most of these guidelines are supported by the Army Office of the Surgeon General and updated military policies are in the development stages. The Army and Navy do not currently support the use of a DNA-PAP (HPV-DNA testing on all Pap tests) screening test for women over 30 years of age. This decision is based upon a joint military service study:

Bidus MA, Maxwell GL, Kulasingam S, Rose GS, Elkas JC, Chernofsky M, Myers ER.
Cost-effectiveness analysis of liquid-based cytology and human papillomavirus testing in cervical cancer screening. *Obstet Gynecol*. 2006 May;107(5):997-1005.

The US Army will begin offering HPV-DNA testing (without associated Pap testing) for special clinical circumstances in April 2008.

INDICATIONS FOR HIGH-RISK HPV DNA TESTING:

HPV-DNA test only (without Pap) 12 months after the clinical visit for the following populations of women:

- ASC-US, HPV+ but colposcopy negative
- ASC-H *without* CIN 2,3 on initial colposcopy
- LSIL *without* CIN 2,3 on initial colposcopy
- Atypical Glandular Cells* *following initial negative colpo-directed biopsies*- at 6 mo if initial HPV positive, or at 12 mo if initial HPV negative
  (NOTE: Pap should also be performed, but as a separate test "without reflex", at 6 & 12 months)
- Definitively treated (by LEEP/Cone) for HSIL or AGC (at 6 months)

**Atypical glandular cells includes atypical endocervical and endometrial cells. Atypical Glandular Cells, Favor Neoplastic and Endocervical Adenocarcinoma in Situ should be followed with a diagnostic cone excision if initial biopsies are negative. Atypical Endometrial Cells should result in an endometrial biopsy.*

The HPV-DNA only test is performed using **Digene's HC2 DNA Collection Device** (a brush). Instructions on collection and procurement are below. This test is not FDA-approved to be performed from a ThinPrep vial without a Pap test. Only Digene kits are accepted as appropriate procurement media for HPV-only testing.

High-risk HPV DNA testing for subsequent management should not be repeated before 12 months, *except for AGC or AIS Pap diagnosis when no pathology is found on the initial colposcopy, endocervical sampling or endometrial sampling*. In this situation, repeat testing at 6 months may be appropriate.

ENCL 2

"Reflex" HPV test in conjunction with the Pap test is performed automatically, as ordered by the pathologist, and is based upon the Pap test result in the following cases:

- ASC-US Pap in women ≥ 21 years of age
- LSIL PAP in women ≥ 45 years of age (postmenopausal)*
- Atypical Glandular Cells- initial diagnosis

** Because postmenopausal status is difficult to determine and often not offered in the clinical history, an arbitrary age of ≥ 45 years is used as a substitute in the military.*

Situations where HPV Testing is not appropriate

- Patients with a prior HPV test (either positive or negative) within the past year (except in cases of atypical glandular cells; see above).
- Routine cervical cancer screening.
- Considered *"unacceptable"* in the management of adolescents (age 20 and younger) with a cytologic diagnosis of ASC-US or LSIL. Further, if HPV testing is inadvertently performed, the results should NOT be used to influence patient management.
- Initial triage of women with HSIL or ASC-H.
- Initial triage of women with Atypical Glandular Cells (AGC) or Adenocarcinoma-in-Situ (AIS) (if used alone).

Testing for low-risk (non-oncogenic) HPV types has no role in routine cervical cancer screening or for the evaluation of women with abnormal cervical cytology.

HPV-DNA Test Only on Cervical Samples:
Specimen must be submitted using the **HC2 DNA Collection Device** available through Digene Corporation (Digene's catalog # 5126-1220.) Clinics may purchase their own kits to have on hand. Order "Direct HPV" in CHCS for the HPV-only test.

Digene HC2 DNA Collection Device Instructions:
1. First remove excess mucus from the cervical os and surrounding ectocervix using a cotton or polyester swab. Discard this swab.
2. To obtain the specimen, insert the Digene Cervical Sampling Brush 1.0-1.5 centimeters into the cervical os until the largest bristles touch the ectocervix. Do not insert brush completely into the cervical canal. Rotate brush **3 full turns** in a counterclockwise direction, remove from the canal.
3. Insert brush into the transport tube. Snap off shaft at scored line, leaving brush end inside tube, and recap securely by snapping in place.

4. **The Collection Device must be kept refrigerated. If shipping to WRAMC, please ship with cold packs.**

NOTE: *Digene's HPV test is not FDA-approved for vaginal specimens; these specimens will not be tested if submitted. It is also not FDA-approved as a stand-alone test from the ThinPrep vial; these specimens will also be rejected.*

At Walter Reed, HPV results will be reported both in CHCS and as an amendment to the original Pap report, if applicable. If an HPV is not indicated as reflex, order the Pap test "without reflex"

OCT 04

Network Infrastructure Services Agency (NISA)
For ACCESS TO WOMEN'S READINESS MODULE
LOGONID REQUEST FORM

For MEDPROS Read Access, go to http://www.mods.army.mil and click on MEDPROS.

Please fax this form to the MODS Support Team, Attn: Help Desk, (703) 681-4983. Improper submissions and illegible forms will be returned.

PART A

1. FULL NAME _____ 2. SSN _____
(LAST) (FIRST) (MI)

3. RANK/GRADE _____ 4. COMPONENT **(MARK ONE)** ___Active Army ___National Guard ___Reserve ___DA Civilian ___Contractor

5. ORGANIZATION / UNIT _____ 6. OFFICE SYMBOL _____

7. OFFICE PHONE: (COMMERCIAL) (_____)_____ DSN: _____

8. STATE ANY PREVIOUS NISA LOGONIDS ISSUED: _____

9. AKO EMAIL ADDRESS:_____
(REGISTER FOR AKO: HTTP://WWW.US.ARMY.MIL)

PART B

I certify that I have read, understand, and will comply with the security policies and procedures described in the "User Responsibilities" section of this form. I know that any violations of these procedures by me, any unauthorized use of Government resources, or withholding knowledge of any suspected violation may result in termination of user privileges on the NISA system and submission of a report to my supervisor.

SIGNATURE_____ DATE _____

PART C - SECURITY VERIFICATION

****Minimum requirement is at least an "Initiated" National Agency Check (NAC)****

1. I certify that _____ holds a valid clearance level of _____

Issued _____ by _____
(DD/MM/YY) (ISSUING AGENCY)

Type of investigation _____Circle one of the following: **COMPLETED** OR **INITIATED** Date _____

Security Manager _____
(TYPE/PRINT NAME) (SIGNATURE) (PHONE#)

2. UNIT MAILING ADDRESS _____

_____
(STREET ADDRESS, P.O. BOX)

_____
(CITY) (STATE) (ZIP)

3. LIST OTHER SYSTEMS/ MODULES TO ACCESS: _____

(Required for MEDPROS Users only)

PART D – COMMANDER (Active Army) or State/RRC Approval Authority (Guard and Reserve)

**** A Commander or SRP OIC is the approval authority for DA Civilians and Contractors ****

I approve the above named person to receive MEDPROS "Write Access" as the commander's representative and further certify that the applicant has met the minimum security requirement (NAC Initiated) and has been briefed by the Information Systems Security Officer (ISSO). He/She understands the data contained within the MODS/MEDPROS Mainframe and Web is for Official Use Only and is not intended and cannot be used for any other purpose.

Allow user to update physicals in MEDPROS (Guard and Reserve only): (CIRCLE ONE) Approved Disapproved

_____
(RANK) (TYPE/PRINT NAME) (POSITION TITLE) (SIGNATURE) (PHONE#)

QUESTIONS

1. **What is Write Access to MEDPROS?** Write Access to MODS/MEDPROS gives the user the ability to update data within any of the MEDPROS Data input Systems: MEDPROS Mainframe/QWS3270, Remote Information Data Entry System (RIDES), MEDPROS Data Entry (MERANT) located on MEDPROS Dashboard and the MEDPROS Web Data Entry (for SRP Sites only). Data Entry includes updating immunizations, medical readiness indicators, building task forces and posting physicals (Guard and Reserve only).

2. What is Read Access to MEDPROS? Read Access to MEDPROS gives the user the ability to view reports on Anthrax compliance, Immunization Tracking, Individual/Unit Medical Readiness Reports, HIV, DNA, Dental, Pre/Post Deployment Health Assessment and the All-Army Command Drilldown. Users cannot update data with Read Access.

INSTRUCTIONS

PART A

#6. Use official organization and office symbol. Contractors must enter COTRs Office Symbol.

#9. You must provide your AKO email address (commercial addresses will not be accepted ie. Hotmail, yahoo, aol, etc.). Contractors can obtain an AKO Account by registering at http://www.us.army.mil.

PART B

ALL APPLICANTS MUST READ AND SIGN.

PART C

1. Personnel must have at least an initiated NAC with date, verified by their security office.
2. You may not verify your own security information.
3. Unit's complete mailing address. Include room and building numbers required if return mail is needed.

PART D

1. Any officer in a Command position (authorized to sign as the unit commander) may grant write access to MEDPROS for Active Army soldiers, DA Civilians and Contractors.

2. Guard/Reserve soldiers must have their State/RRC Approval Authority grant write access to MEDPROS. The only exception is those soldiers that have been mobilized or are deployed. In this situation, any officer in a Command position may grant write access.

4. **CONTRACTORS** are also required to submit a Visit Authorization Request **(VAR)** signed by their Corporate Security Officer. The VAR can be found on the next page and be on the Contracting Companies Letterhead or their full name and address on the top of the form.

Please fax or email the NISA form to: MODS Support Team ATTN: MODS Help Desk, Comm: (703) 681-4983 or MODS-Help@asmr.com

USER RESPONSIBILITIES

A. Adhere to security requirements for all remote terminals, individual passwords, and data transmitted to and from the NISA ADP Systems.

B. Handle all information from the NISA data base containing personal privacy act information as sensitive data and comply with provisions of the Privacy Act and other published security procedures.

C. Follow proper LOGON and LOGOFF procedures.

D. Ensure each remote terminal is active only when an authorized terminal operator is present and using the equipment. Any violation of this procedure is a breach of security. Prior to leaving the terminal, each user must properly LOGOFF to ensure access cannot be gained without initiating proper LOGON procedures.

E. Prevent unauthorized disclosure or transfer of systems entry features from one user to another. DO NOT SHARE TERMINAL SESSIONS or PASSWORDS. Violations of this will result in suspension from access.

F. Do not transmit and/or extract classified data via unclassified remote terminals.

G. Report suspected security violations to your supervisor and Security Manager.

H. Do not attach privately owned equipment to the NISA computers.

I. Fill out the NISA LogonID Request form completely, incomplete forms will be returned.

J. Change PASSWORDS at least once every 90-day period. The PASSWORDS are computer generated, but the process must be initiated by the user.

MUST BE ON CONTRACTING COMPANY LETTERHEAD

To: ASM Research, Inc.
ATTN: MODS Support Team
3025 Hamaker Court, Suite 100
Fairfax, VA 22031
Fax # 703.681.4983 DSN 761.4983

(This form is only required for Contractor's)
VISITOR ACCESS REQUEST (VAR)

Questions 1 – 5 are REQUIRED for all access requests.

1) Name and Address of Agency to be visited: MODS, ASM Research, Inc.

2) Name of Visitor:
Date of Birth:
Place of Birth:
Citizenship:
SSN:

3) Job Title of Visitor:

4) Period of Visit (To and From Dates):

5) Purpose and Justification for visit (Job description and applications requested. IE: MODS/MEDPROS, PERSONNEL Web, …):

6) Type of Investigation and Date:
Investigation Completed/Initiated By:

COGNIZANT SECURITY OFFICE:
(Fill in if Security Clearance info is filled in)

Initiating Security Office Address:

I certify that the security clearance granted this facility and the security clearance granted the person listed above are correct as stated.

Name of Facility Security Officer (Sign if Clearance information is filled in)

NEED TO KNOW FOR THIS VISIT IS CERTIFIED AS VALID

Visitor's Project Manager/ Project/ Organization / Phone Number **(Required)**